UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ROBERT LAWTON, THOMAS PATRICK O'CONNOR JR., BARBARA ANN BARTOL, and PAUL SCOTT MacHENRY

Appeal No. 2005-1610[1]
Application No. 10/054,354

HEARD: November 17, 2005

Before MILLS, GRIMES, and GREEN, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 1-8, which are all of the claims pending in this application. We note claims 7 and 8 have not been rejected over the prior art.

Claim 1 is illustrative of the claims on appeal and reads as follows:

1. A composition of matter comprising an isolated polypeptide consisting essentially of SEQ ID NO:1 and amino acid substitution variants thereof that specifically bind to an anti-Ehrlichia antibody.

[1] We note this application is related to Serial No. 09/765,739, Appeal No. 2005-2708 and Serial No. 10/054,647, Appeal No. 2005-1593. Appeals in both of these applications were also heard on November 17, 2005.

2. The composition of claim 1, further comprising a carrier.

3. An article of manufacture comprising packaging material and, contained within the packaging material, a polypeptide consisting essentially of SEQ ID NO: 1 or amino acid substitution variants thereof that specifically bind to an anti- Ehrlichia antibody.

4. The article of manufacture of claim 3 wherein the packaging material comprises a label that indicates that the polypeptide can be used for the identification of Ehrlichia infection in a mammal.

5. An article of manufacture, comprising packaging material and, contained within the packaging material, a polypeptide consisting essentially of SEQ ID NO: 1 or amino acid substitution variants thereof that specifically bind to an anti-Ehrlichia antibody, wherein the packaging material comprises a label that indicates that the polypeptide can be used for identification of Ehrlichia infection in a mammal, and wherein the label indicates that the identification of an Ehrlichia infection is done using a method of detecting presence of antibodies to Ehrlichia comprising:

   (a) contacting a polypeptide consisting essentially of SEQ ID NO: 1, or amino acid substitution variants thereof that specifically bind to an anti-Ehrlichia antibody, with a test sample suspected of comprising antibodies to Ehrlichia, under conditions that allow polypeptide/antibody complexes to form;

   (b) detecting polypeptide/antibody complexes; wherein the detection of polypeptide/antibody complexes is an indication that an Ehrlichia infection is present.

6. An article of manufacture comprising packaging material and, contained within the packaging material, a polypeptide consisting essentially of SEQ ID NO: 1 or amino acid substitution variants thereof that specifically bind to an anti-Ehrlichia antibody, wherein the packaging material comprises a label that indicates that the polypeptide can be used for identification of Ehrlichia infection in a mammal, and wherein the label indicates that the Ehrlichia infection is caused by Ehrlichia canis or Ehrlichia chafeensis.

7. A composition of matter comprising an isolated polypeptide that is 20 amino acids in length, which comprises SEQ ID NO: 1 or amino acid substitution variants thereof, wherein the polypeptide specifically binds to an anti-Ehrlichia antibody.

8. An article of manufacture comprising packaging material and, contained within the packaging material, an isolated polypeptide that is 20 amino acids in length, which comprises SEQ ID NO: 1 or amino acid substitution variants thereof, wherein the polypeptide specifically binds to an anti-Ehrlichia antibody.

The prior art references cited by the examiner are:

Rikihisa et al. (Rikihisa) WO 99/13720 Mar. 25, 1999

Waner et al. (Waner), "Comparison of a Clinic-based ELISA test kit with the Immunofluorescence test for the Assay or Ehrlichia canis antibodies in Dogs," Journal of Veterinary Diagnostic Investigation, Vol. 12, pp. 240-244 (2000)

Grounds of Rejection

Claims 1-8 stand rejected under 35 U.S.C. § 112, first paragraph for lack of written description.

Claims 1-8 stand rejected under 35 U.S.C. § 112, first paragraph for lack of enablement.

Claims 1-3 stand rejected under 35 U.S.C. § 102(a), as anticipated by Rikihisa.

Claims 1-6 stand rejected under 35 U.S.C. § 103(a), as obvious over Rikihisa in view of Waner.

We reverse the rejection for lack of written description and enablement and affirm the rejections for anticipation and obviousness.

Claim Grouping

For each rejection appellants do not argue individual claims separately. Brief, page 2. Therefore, we treat each statutory grounds of rejection separately, and select claim 1 as representative of the claims on appeal for each rejection before us. 37 CFR § 1.192(c)(7)(2004), now 37 CFR § 41.37(c)(1)(vii) (September 13, 2004).

DISCUSSION

Claim Interpretation

Our appellate reviewing court stated in Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1567-1568, 1 USPQ2d 1593, 1597 (Fed. Cir.), cert denied, 481 U.S. 1052 (1987):

> Analysis begins with a key legal question -- what is the invention claimed? Courts are required to view the claimed invention as a whole. 35 U.S.C. 103. Claim interpretation, in light of the specification, claim language, other claims and prosecution history, is a matter of law and will normally control the remainder of the decisional process. [Footnote omitted.]

To that end, we also note that during ex parte prosecution, claims are to be given their broadest reasonable interpretation consistent with the description of the invention in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); In re Crish, 393 F.3d 1253, 1256, 73 USPQ2d 1364, 1367 (Fed. Cir. 2004). Moreover, it is well-established that "'[c]omprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and

still form a construct within the scope of the claim." Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997).

In addition, for the purposes of searching for and applying prior art under 35 U.S.C. §§ 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG Industries v. Guardian Industries, 156 F.3d 1351, 1355, 48 USPQ2d 1351, 1355 (Fed. Cir. 1998) ("PPG could have defined the scope of the phrase 'consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention.").

As background, according to the specification

> [t]he invention provides highly purified reagents for the detection of *E. canis and E. chaffeensis* antibodies and antibody fragments. In particular, the invention provides polypeptides having at least 85% identity, more preferably at least 90% identity, and still more preferably at least 96%, 97%, 98%, or 99% identity to a polypeptide sequence shown in SEQ ID N0s:1-7. See Table 1. Polypeptides that do not comprise 100% identity to a polypeptide sequence shown in SEQ ID N0s:1-7 are considered "variants," and are considered polypeptides of the invention.

Specification, page 5.

> Besides conservative amino acid substitution, variants of the present invention include: (I) substitutions with one or more of the non-conserved amino acid residues, where the substituted amino acid residues may or may not be one encoded by the genetic code; (ii) substitution with one or more of amino acid residues having a substituent group; (iii) fusion of the mature polypeptide with another compound, such as a compound to increase the stability and/or solubility of the polypeptide *(e.g.,* polyethylene glycol); (iv) fusion of the polypeptide with additional amino acids, such as an IgG Fc fusion region peptide, a leader or secretory

sequence, or a sequence facilitating purification.

Specification, pages 8-9.

Claim 1 is directed to "a composition of matter comprising an isolated polypeptide consisting essentially of SEQ ID NO:1 and amino acid substitution variants thereof that specifically bind to an anti-Ehrlichia antibody." What is clear from the language of claim 1 is that appellants claim only amino acid substitution variants of SEQ ID NO:1 and that the claims do not encompass amino acid insertion or deletion variants within the sequence of SEQ ID NO:1. Furthermore, we construe the phrase "consisting essentially of" in claim 1, to be equivalent to the term "comprising" because appellants have not specifically defined the basic and novel characteristics of the sequence in the patent application specification. Thus, while claim 1 does not include amino acid insertion or deletion variants within the sequence of SEQ ID NO:1, claim 1 does include within its scope polypeptides with additional amino acids at either end of SEQ ID NO:1, such as a whole protein that binds an anti-Ehrlichia antibody. Further, consistent with the specification, amino acid substitution variants of SEQ ID NO:1 have at least 85% sequence identity with SEQ ID NO:1. Specification, page 5.

Written Description

Claims 1-8 stand rejected under 35 U.S.C. § 112, first paragraph for lack of written description.

According to the examiner (Answer, page 4),

> The specification broadly describes as a part of the invention a composition and an article of manufacture comprising the isolated polypeptide of SEQ ID No: 1 and variants thereof. The specification states that "variants in which amino acids of the polypeptides of the invention are substituted, deleted or added in any combination are contemplated by the invention". The specification also states " that naturally occurring variants and non-naturally occurring variants are included in the invention and may be produced by mutagenesis techniques or by direct synthesis" (page 7.) Applicant has broadly described the invention as embracing any substitution, insertion or deletion change of amino acids throughout the length of the polypeptide sequence. Variants of, SEQ ID No:1 correspond to sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a variant degree of identity (similarity, homology), and so forth. None of these sequences meet the written description provision of 35 U.S.C. 112, first, paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

In response, Appellants argue that the examiner has improperly interpreted the claim scope and that they have provided a representative number of species to support the written description of the pending claims. With respect to claim interpretation, Appellants argue that, "the partial structure of the claimed [amino acid substitution] variants are known, i.e., sequences that hav[e] at least 85% identity to SEQ ID NO: 1. ... Therefore, the [claimed] variants have at least 17 amino acids in common with the 20 amino acid long SEQ ID NO:1." Appeal Brief, pages 9-10.

As discussed herein, we agree with appellants that the amino acid substitution variants of SEQ ID NO:1 recited in claim 1 are those that have at least 85% sequence

identity with SEQ ID NO:1. Having addressed the scope of the claim which must meet the written description requirement, we review the merits of the written description rejection before us.

Appellants take the position (Brief, page 10) that Table 1 of the specification:

> demonstrates that positions 3, 8, and 13 of SEQ ID NO:1 are highly conserved across the seven sequences (dark gray columns). Additionally, positions 1,4, 5, 6, 7, 9, 10, 11, 12, and 15 are partially conserved across the 7 sequences (light gray columns). That is, only 2 different amino acids appear in these positions. For instance, only K or N appear as amino acids in position 1 across the seven sequences. One of skill in the art would recognize that variants should likely retain the amino acids at positions 3, 8, and 13 and that one of two amino acids should likely be present at positions 1,4, 5,6, 7, 9, 10, 11, 12, and 1 5. One of skill in the art would also recognize that amino acids at position 2, 14, and 16-20 could tolerate a greater range of amino acid substitutions.
>
> Therefore, the specification provides structural guidance for the claimed variants. Each of the claims recite that the isolated polypeptides specifically bind to an anti-Ehrlichia antibody. The physical properties and functional characteristics of the variants are also disclosed by the specification. That is, the specification teaches that the variants specifically bind to an anti-Ehrlichia antibody and also teaches how to test if such variants specifically bind to an anti-Ehrlichia antibody. See specification page 10, line 6 through page 11, line 6; page 1, line 21 - page 16, line 8; Example 1. Methods of making the variants of SEQ ID NO:1 are well-known in the art and are described in the specification. See e.g, page 5, lines 7-14; page 6, line 3 through page 7, line 5; page 7, line 12 through page 9, line 7; page 18, line 19 through page 19, line 13; page 7. One of skill in the art could make and test variants of invention given the specification and the knowledge in the art.

Thus, appellants argue "one of skill in the art would recognize that the Applicants were in possession of the necessary common attributes or features of the elements

possessed by the members of the genus in view of the species disclosed because the partial structure, physical and/or chemical properties, functional characteristics, and methods of making the claimed variants is disclosed in the specification." Brief, page 11.

"The 'written description' requirement serves a teaching function, . . . in which the public is given 'meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.'" University of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 922, 69 USPQ2d 1886, 1891 (Fed. Cir. 2004) (citation omitted). Another "purpose of the 'written description' requirement is . . . [to] convey with reasonable clarity to those skilled in the art that, as of the filing date [ ], [the applicant] was in possession of the invention." Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). See also Enzo Biochem Inc. v. Gen-Probe Inc., 296 F.3d 1316, 1329, 63 USPQ2d 1609, 1617 (Fed. Cir. 2002). The requirement is satisfied when the specification "set[s] forth enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed." University of Rochester, 358 F.3d at 928, 69 USPQ2d at 1896. Whether or not a specification satisfies the requirement is a question of fact, which must be resolved on a case-by-case basis (Vas-Cath, 935 F.2d at 1562-63, 19 USPQ2d at 1116), and it is the examiner's "initial burden [to] present[ ] evidence

or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims" (In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976)).

"[A]pplicants have some flexibility in the 'mode selected for compliance' with the written description requirement" (University of Rochester, 358 F.3d at 928, 69 USPQ2d at 1896); it is well settled that actual reduction to practice is not necessary to satisfy the requirement (id., at 926, 69 USPQ2d at 1894). In University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), the court discussed the application of the written description requirement to inventions in the field of biotechnology, stating that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. at 1567, 43 USPQ2d at 1405. The court also stated that

> a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. at 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material

generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material" (id.), but "[a] description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

Subsequently, the court clarified that "[not] all functional descriptions of genetic material fail to meet the written description requirement," for example, "the written description requirement would be met for [a claim] . . . if the functional characteristic . . . were coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed." Enzo Biochem, 296 F.3d at 1324-25, 63 USPQ2d at 1613.

Here, all of the polypeptides in the claimed genus have a certain amount of structural commonality (all encode a polypeptide that includes an amino acid substitution variant within the sequence of SEQ ID NO:1), all amino acid substitution variants within the polypeptide of SEQ ID NO:1 have at least 85% sequence identity with SEQ ID NO:1, and all encode proteins which have at least one defined functional characteristic, they specifically bind to anti-Ehrlichia antibody. Specification, page 1.

The specification would reasonably appear to describe methods of isolating and preparing polypeptides which are amino acid substitution variants of SEQ ID NO:1 having at least 85% identity to SEQ ID NO:1 and to describe assays which confirm their ability to bind to anti-Ehrlichia antibodies. Specification, pages 7-8, and 16. Again, as explained in Lilly, a genus of polynucleotides can be described by a representative number of polynucleotides, defined by sequence, or sharing common structural features which constitute a substantial portion of the genus; and, as explained in Enzo, a genus may be described by means of a functional characteristic coupled with a disclosed correlation between that function and a known or disclosed structure. Whether the level of disclosure in the specification would have allowed one skilled in the art to recognize that the inventor invented what is claimed is a question of fact. The USPTO has summarized a number of factors to be considered in making this determination; they include "the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention." Guidelines for Examination of Patent applications Under the 35 U.S.C. § 112, ¶ 1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001). "Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." Id.

We agree with the Appellants that the examiner has misinterpreted the scope of claim 1. We do not agree with the examiner's assertion that "Applicant has broadly described the invention as embracing any substitution, insertion or deletion change of the amino acids" within the entire length of the polypeptide sequence of SEQ ID NO:1. Answer, page 4. The claims clearly indicate that they include only amino acid substitution variants of SEQ ID NO:1. Because the claims have not been properly interpreted by the examiner, the legal foundation on which the rest of the examiner's written description rejection is set, is not directly on point. Thus we do not find the examiner has established a prima facie case of lack of written description. Nor do we find that the examiner has sufficiently addressed appellants' arguments concerning claim scope or the specification's teaching of a representative number species which generally support the written description of the subject matter of claim 1.

Thus, the examiner's arguments are insufficient to establish a prima facie case of lack of written description or that one skilled in the art would not have recognized that appellants were in possession of what is claimed. Accordingly, the rejection is reversed.

Enablement

Claims 1-8 stand rejected under 35 U.S.C. § 112, first paragraph for lack of enablement.

"The scope of [patent] claims must be less than or equal to the scope of the enablement. The scope of enablement, in turn, is that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art without undue experimentation." Nat'l Recovery, 166 F.3d 1190, 1196, 49 USPQ 2d 1671, 1675 (Fed. Cir. 1999); see also In re Goodman, 11 F.3d 1046, 1050, 29 USPQ2d 2010, 2013 (Fed. Cir. 1993) ("[T]he specification must teach those of skill in the art 'how to make and how to use the invention as broadly as it is claimed'."); In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) ("[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art."). Invitrogen Corp. v. Clonetech Laboratories, Inc., 429 F.3d 1052, 1070 (Fed. Cir. 2005).

"It is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. In re Angstadt, 537 F.2d 498, 502-03, 190 USPQ 214, 218 (CCPA 1976). However, there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility." In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

It is the examiner's position that (Answer, page 6)

> the specification, while being enabling for a composition of matter and an article of manufacture that comprises an isolated polypeptide shown in SEQ ID No:1, does not reasonably provide enablement for a composition or an article of manufacture that comprises variants of SEQ ID. No:1. ... The specification is enabling only for the polypeptides of SEQ ID NO:1 as disclosed in the specification. The specification states that "variants in which amino acids of the polypeptides of the invention are substituted, deleted or added in any combination are contemplated by the invention". The specification also states "that naturally occurring variants and non-naturally occurring variants are included in the invention and may be produced by mutagenesis techniques or by direct synthesis" (page 7). The specification teaches that there are many tolerable and conservative amino acid substitutions which can be made that are not critical to protein function (pages 7-9). There is no guidance provided as to which amino acids can be added, deleted or substituted and the polypeptide would retain its biological function. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides broadly encompassed by the claims and the claims broadly encompass a significant number of inoperative species.

As discussed above with respect to the written description rejection, in our view the examiner has misinterpreted the claims, arguing they encompass all variants of SEQ ID NO:1, including amino acid insertion and deletion mutants within SEQ ID NO:1. What is clear from the language of claim 1 is that appellants claim only amino acid substitution variants within SEQ ID NO:1 and that the claims do not encompass amino acid insertion or deletion variants within the sequence of SEQ ID NO:1.

In our view, the examiner has not established a prima facie case of lack of enablement based on the properly interpreted claim scope. Moreover, appellants argue (Brief, pages 12-13) that the specification provides a structural description of the claimed variants, and provides information regarding conserved amino acids in the claimed sequence. It is the appellants' position that the specification, including this disclosure, provides one of ordinary skill in the art with the necessary information to make substitution variants of SEQ ID NO:1, having at least 85% identity with SEQ ID NO:1, and which maintain their binding ability to anti-Ehrlichia antibody without undue experimentation. We do not find that the examiner has properly addressed these arguments of appellants or provided evidence of lack of enablement or inoperative embodiments within the relevant claim scope.

The rejection of the claims for lack of enablement is reversed.

Anticipation

Claims 1-3 stand rejected under 35 U.S.C. § 102(a), as anticipated by Rikihisa.

Our interpretation of the claim language for purposes of 35 U.S.C. § 102 is set forth in the claim interpretation section above.

The examiner finds Rikihisa teaches the isolated polypeptide shown in SEQ ID NO:1 in Fig. 21B. Answer, page 9.

Appellants take the position that (Brief, page 13)

> [t]he claims are drawn to compositions and articles of manufacture comprising an isolated polypeptide consisting essentially of SEQ ID NO:1 and an amino acid substitution variant thereof. The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s) of the claimed invention." See, In re Herz, 190 USPQ 461,463 (CCPA 1976) (emphasis in original); MPEP § 2111.03. The claims recite an isolated E. canis polypeptide, i.e., a portion or fragment of the whole protein. Rikihisa does not teach or suggest polypeptide portions or fragments. The claimed isolated polypeptides are useful, inter alia, to detect the presence of anti-Ehrlichia antibodies. The polypeptides can be used as reagents in assays that provide greater sensitivity than the reagents taught in Rikihisa (i.e., whole, recombinant proteins).

However, upon review of the specification we do not find that appellants have attributed a specific meaning to the phrase "consisting essentially of" or that they have identified any basic and novel characteristics of SEQ ID NO:1, other than the characteristic that it binds anti-Ehrlichia antibody. Therefore, absent a clear indication in the specification or claims of what the basic and novel characteristics of the claimed sequence actually are, the "consisting essentially of" in claim 1 will be construed as equivalent to "comprising." See, e.g., PPG Industries 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996). While we note appellants' argument and Declaration under 37 CFR § 1.132, that the "addition of amino acids to the claimed isolated polypeptides so that they encompass whole Ehrlichia proteins would materially affect the basic and novel characteristics of the polypeptides" and that the claimed polypeptides exhibited a greater sensitivity and specificity than whole, partially purified Ehrlichia proteins, we do not agree with appellants' claim interpretation. Reply Brief,

When we construe the term "consisting essentially of" as equivalent to "comprising" for purposes of determining whether the sequence of SEQ ID NO:1 reads on the whole protein described by Rikihisa, we answer this question in the affirmative. Thus, we find that Claim 1 of the present application reads on the prior art, whole Ehrlichia proteins of Rikihisa (Fig. 21B).[2]

Therefore, we affirm the rejection of claims 1-3 as anticipated by Rikihisa.

Obviousness

Claims 1-6 stand rejected under 35 U.S.C. 103(a), as obvious over Rikihisa in view of Waner.

As evidentiary support for the obviousness rejection, the examiner relies on Rikihisa (discussed above) and Waner, and argues that (Answer, page 10)

> Rikihisa et al teach diagnostic tools for veterinary and human use which are used for serodiagnosing ehrlichiosis in mammals (see the Abstract). Rikihisa et al teach compositions of matter and articles of manufacture which such as a column, plastic dish, matrix or membrane preferably nitrocellulose containing an isolated outer membrane proteins of E. chaffeensis or E. canis. used in a diagnostic method of detecting antibodies to the E. chaffeensis or E. canis in a sample of bodily fluid from

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[2] Compare, In re Crish, 393 F.3d 1253, 1256, 73 USPQ2d 1364, 1367 (Fed. Cir. 2004) [the reasonable interpretation of the claims containing both of the terms "comprising" and "consists" is that the term "consists" limits the "said portion" language to the subsequently recited numbered nucleotides, but the earlier term "comprising" means that the claim can include that portion plus other nucleotides. Read in context, the claims thus do not preclude a DNA sequence having additional nucleotides.]

> a patient (page 11). Rikihisa et al teach the isolated polypeptide shown in SEQ ID NO:1, (see Figure, 21.B). Rikihisa et al do not teach the use of a label indicates that the polypeptide can be used for the identification of Ehrlichia infection in a mammal. Waner et al teaches a label that indicates the use of the composition of matter or the article of manufacture (page 241, Figure 1).

The Examiner concludes (Answer, pages 10-11)

> It would be prima facie obvious at the time the invention was made to add a label as taught by Waner et al to the composition of matter or article of manufacture of Rikihisa et al because it is well known in the art to include packing material and a label to indicate the intended use of the composition of matter or article of manufacture.

We agree, based on the evidence presented and discussion of Rikihisa herein, that the examiner has established a prima facie case of obviousness.

In rebuttal, appellants present similar argument regarding Rikihisa as put forth in the anticipation rejection, namely that Rikihisa does not teach isolated polypeptides or variants as claimed. As indicated with respect the anticipation rejection in view of Rikihisa, we do not agree with appellants' claim interpretation and instead find that the claims read on the prior art whole proteins of Rikihisa. In view of the above, we do not find appellants have presented sufficient evidence or argument to rebut the examiner's prima facie case of obviousness.

CONCLUSION

The rejection of claims 1-8 under 35 U.S.C. § 112, first paragraph for lack of written description is reversed. The rejection of claims 1-8 under 35 U.S.C. § 112, first

paragraph for lack of enablement is reversed. The rejection of claims 1-3 under 35 U.S.C. § 102(a), as anticipated by Rikihisa is affirmed. The rejection of claims 1-6 under 35 U.S.C. § 103(a), as obvious over Rikihisa in view of Waner is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR §1.136(a). No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

DEMETRA J. MILLS
Administrative Patent Judge

ERIC GRIMES
Administrative Patent Judge

LORA M. GREEN
Administrative Patent Judge

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